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REMARKS

Claims 1-39 are in this application. In the Office Action dated September 13, 2006, the Examiner defined two subgenera within the claims:

> **G1:** the objective of the treating is one of the following: to treat diabetes, prevent the onset of overt diabetes, to treat impaired glucose tolerance, to achieve glucose homeostatis, to prophylactically spare *beta*-cells, to prevent *beta*-cell death, to prevent or mitigate *beta*-cell dysfunction, to reduce the incidence of hyperinsulinemia caused by chronic dosing of insulin, to reduce the concentration of blood glucose after oral administration, to decrease C-peptide levels, or to decrease insulin levels; and
>
> **G2:** The objective of the treating can be whatever the claims permit, provided that G1 is excluded.

The Examiner stated that claims 1-39 comprise four (4) distinct inventions and required that the application be restricted, under 35 U.S.C. § 121, to one of these inventions as follows:

I) Claims 1-25, 29, 38, 39 drawn to a method of treating a mammal, limited to G1.

II) Claims 1, 5-8, 11-15, drawn to a method of treating a mammal, limited to G2.

III) Claims 26-28, drawn to a method of prolonging the effect of oral administration of insulin.

IV) Claims 30-37, drawn to a method of prolonging the effect of oral administration of insulin at a time when applicants believe that the skilled immunochemist would be unable to detect the presence of insulin in the bloodstream.

In addition, the Examiner required under 35 U.S.C. § 121 that Applicants elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. In particular, the Examiner required that, whichever invention group is chosen, Applicants also elect one objective of treatment, a specific insulin type and the contents of the formulation.

In response, Applicants elect for examination Group I, consisting of claims 1-25, 29, 38, 39 drawn to a method of treating a mammal. Accordingly, Applicants herein cancel claims 26

and 30 without prejudice to Applicants' right to reintroduce them at a later date or in a divisional application, and amend claims 27, 28, 31 and 34-37 to make them dependent upon claim 1.

With respect to the election of species requirement, Applicants elect the following for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable:

- the treatment of Diabetes as the specific objective,
- recombinant human Insulin as the specific insulin type (Applicants point to paragraph [00104] of the specification for support), and
- the formulation of recombinant human Insulin, 4-CNAB and pharmaceutically acceptable excipients as the contents of the formulation.

According to currently recommended U.S. Patent and Trademark Office policy, the Examiner is specifically authorized to contact the undersigned in the event that a telephone interview would advance the prosecution of the case.

Respectfully submitted,
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